(3)

No. 04-695

IN THE

Supreme Court of the United States

HOUSEY PHARMACEUTICALS, INC.,
Petitioner,

v.

MERCK & CO., INC., ASTRAZENECA UK LTD., ASTRAZENECA LP, ASTRAZENECA PHARMACEUTICALS LP, AVENTIS PHARMACEUTICALS, INC., BRISTOL-MYERS SQUIBB COMPANY, ROCHE HOLDINGS, INC., HOFFMANN-LA ROCHE INC., ROCHE LABORATORIES, INC., SYNTEX (U.S.A.) INC., WYETH, and WYETH PHARMACEUTICALS INC.,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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REPLY BRIEF FOR PETITIONER

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TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES	ii
ARGUMENT	2
CONCLUSION	10

TABLE OF AUTHORITIES

CASES	Page
Akron Polymer Container Corp. v. Exxel Container, Inc., 148 F.3d 1380 (Fed. Cir. 1998)	9
Allied Colloids Inc. v. American Cyanamid Co., 64 F.3d 1570 (Fed. Cir. 1995)	9
Bayer AG v. Housey Pharms., Inc., 2003 WL 22953817, (D. Del.), *appeal argued Nov. 3, 2004* (Fed. Cir. No. 04-1194)	7
CFMT, Inc. v. Yieldup Int'l Corp., 349 F.3d 1333 (Fed. Cir. 2003)	9
Dayco Prods., Inc. v. Total Containment, Inc., 329 F.3d 1358 (Fed. Cir. 2003)	9
Florida State Bd. Of Educ. v. American Bioscience, Inc., 333 F.3d 1330 (Fed. Cir. 2003)	9
Gambro Lundia AB v. Baxter Healthcare Corp., 110 F.3d 1573 (Fed. Cir. 1997)	9
Halliburton Co. v. Schlumberger Technology Corp., 925 F.2d 1435 (Fed. Cir. 1991)	9
Hoffmann-La Roche, Inc. v. Promega Corp., 323 F.3d 1354 (Fed. Cir. 2003)	9
Juicy Whip, Inc. v. Orange Bang, Inc., 292 F.3d 728 (Fed. Cir.), *cert. denied*, 537 U.S. 1019 (2002)	9
Kingsdown Med. Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867 (Fed. Cir. 1988)	9
Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996)	3
Molins PLC v. Textron, Inc., 48 F.3d 1172 (Fed. Cir. 1995)	9
National R.R. Passenger Corp. v. Pennsylvania P.U.C., 288 F.3d 519 (3d Cir. 2002), *cert. denied*, 538 U.S. 1057 (2003)	10
Phillips v. AWH Corp., 376 F.3d 1382 (Fed. Cir. 2004)	2, 3, 5, 6

TABLE OF AUTHORITIES

	Page
United States v. Adams, 383 U.S. 39 (1966)	2
United States v. Munsingwear, 340 U.S. 36 (1950)	8
Restatement Second of Judgments § 28(2).....	10

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REPLY BRIEF FOR PETITIONER

Respondents' opposition leaves wholly untouched the affirmative case for certiorari: the need for clarification of claim-construction principles, the conflicts over such principles that bear directly on the ruling in this case, and the fact that the patent-destroying construction adopted in this case violates the most fundamental command of proper claim construction, *i.e.*, to adopt a sensible reading that captures the invention. Instead, respondents briefly cite two reasons for denying review. Both are meritless and embody improper

disregard of the importance of preserving patent rights—here, rights that are vitally important to a tiny company, have been licensed by a majority of the world's major research-based pharmaceutical companies, and have contributed to significant advances in recent cancer treatments. Pet. 2-3.

ARGUMENT

I. Respondents' opposition does not take issue with any of the key affirmative reasons for granting review and correcting the decision in this case—either now or after awaiting the Federal Circuit's decision in *Phillips v. AWH Corp.*, 376 F.3d 1382 (Fed. Cir. 2004) (granting *en banc* review of various claim-claim construction issues), which is scheduled for oral argument on February 8, 2005.

A. Respondents do not dispute that there is a need for clarification of fundamental claim-construction principles. The Federal Circuit's own grant of *en banc* review in *Phillips* (reflecting a host of patent-law commentaries) makes any such dispute impossible. Pet. 15-16. Nor do respondents dispute that the decision in this case directly implicates the claim-construction issues set for review in *Phillips* and doctrinal conflicts among Federal Circuit precedents, including on (1) the impermissibility of constructions that render claim language circular or meaningless surplusage, (2) the central importance to a sound claim construction of attending to patents' explanation of the limits of prior art and how the claimed invention overcomes such limits, and (3) the significance of the principle that patent-invalidating constructions be avoided if possible. Pet. 14-15. Finally, respondents nowhere disagree with the petition's showing that a proper context-dependent, substance-driven approach to claim construction—generally supported by the United States as *amicus* in *Phillips*—is found in this Court's precedents, which call for avoidance of invalidating constructions and an approach to claim construction that is centrally focused on "ascertaining the invention" (*United States v. Adams*, 383

U.S. 39, 49 (1966)) through a "necessarily sophisticated analysis of the whole document" (*Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 389 (1996)). *See* Pet. 17-22. In short, the need for review, and ready availability of proper standards for re-establishing a sound approach to claim construction, stand unrebutted.

B. Respondents include all of one footnote in their brief addressing the merits of the ruling in this case. Opp. 5 n.3. That short discussion says nothing to dispute that the ruling here illustrates the very errors of claim-construction principle featured by the petition (and at issue in *Phillips*). It also says literally nothing to rebut the petition's showing that the construction adopted by the majority (1) contradicts ordinary usage and common sense and renders claim language circular and meaningless surplusage, (2) overrides the patents' explanation of the essential advance over prior art, and (3) treats the invalidity-avoidance principle as an insignificant afterthought. Pet. 22-29.

As to *the majority's adopted construction*, respondents note the petition's showing that it is senseless, then immediately change the subject to the merits of *petitioner*'s alternative construction. Opp. 5. They give no answer at all to the showing that the majority's (and district court's) construction produces a nonsensical tautology, contradicting ordinary usage by making the method of screening into a definition of what is being screened for, with perfection attributed to the screening test by *definition* (everything showing the differential effect in the assay is an "inhibitor or activator of a protein"; everything not, not). Construing the assay as definitionally perfect is outlandish in the experimental sciences, where perfection is essentially impossible—as wrong as *defining* "perpetrator" by whoever is picked out of a lineup (or "time" by the result of an occasionally faulty clock). Not surprisingly, the majority's construction contradicts the plain scientific meaning of "method of determining"—adopted by the district court and unchallenged by the Merck group of

respondents—as only indicating the searched-for result by a high probability, not perfection. Pet. 22-24. The majority's (district court's) construction is thus wholly undefended. Yet respondents do not and cannot disagree that the stipulation of invalidity and non-infringement depended entirely on *that* construction, so that error in that construction precluded the Federal Circuit's affirmance of the district court's judgment, regardless of what other construction might be considered. Pet. 8, 22.

As to petitioner's construction, respondents just baldly declare that binding to (directly interacting with) the protein molecule is somehow extraneous to the "inhibitor or activator of a protein" claim limitation. Opp. 5. That declaration wholly ignores the compelling reasons to conclude otherwise. Dictionary definitions show one standard *meaning* of "inhibiting"/"activating" an enzyme to be attaching to the molecule (to affect its action), and there is not the slightest reason for that meaning to be unavailable for proteins generally. Pet. 25. Expert testimony on the claim-construction issue, including from petitioner's adversary, confirms that understanding. Pet. 25.[1] The essence of the patents' distinction of prior-art

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[1] Because respondents have drawn into this case the later proceedings in the *Bayer AG v. Housey Pharms., Inc.* case (Opp. 2, 6)—and Bayer was respondents' joint adversary of petitioner for claim construction—we note that petitioner's construction of "inhibitor or activator of a protein" was directly supported there by Bayer's expert Dr. Fields and Bayer's witness Dr. Hsiao. 12/09/02 Transcript at 822 (Dr. Hsiao: "Q: Okay. Now, did you understand Dr. Housey's patent to be directed to determining whether substances would bind to specific protein? A: Yes."); 12/03/02 Transcript at 144-45 (Dr. Fields) ("Q: Did you understand when you read Dr. Housey's patents in connection with your preparation work for your opinions here Dr. Housey was claiming an ability to identify inhibitors or activators that would directly interact with a specific protein? A: That's my understanding."); *id.* at 61-62, 148-49 (Dr. Fields). Dr. Fields noted "the central ten[et] of pharmacology, which is that for a substance to act on a particular protein or molecule, it needs to first bind to that molecule." *Id.* at 55.

screening methods, moreover, is precisely that they cannot and do not, whereas the newly claimed method can and does, distinguish those substances that alter cellular characteristics by directly interacting with the protein molecule from substances that alter cellular characteristics "'by other mechanisms,'" through action "'upon other cell metabolites.'" Pet. 26. Indeed, Dr. Housey explained to the PTO that "'target protein specificity . . . is the *essential point of the present invention.*'" Pet. 29 (emphasis added). Respondents have no answer for any of these compelling reasons that, not only is the construction adopted by the majority below incorrect, but petitioner's construction soundly captures the claimed invention and is accordingly correct.

II. Respondents make only two arguments against review. Both lack merit.

A. Respondents' first brief ground for opposing certiorari is that the *en banc* Federal Circuit in *Phillips* is currently considering how to resolve the conflicts of claim-construction approach and "there is no reason for the Court to delay resolution of the present case." Opp. 5. But the conclusion does not follow from the premise. Indeed, respondents' submission turns the relevance of *Phillips* on its head and ignores the most elementary demand of fairness.

A denial of certiorari here would be a final judgment of invalidity of Housey's patents and their non-infringement by respondents. Yet respondents nowhere dispute that a different outcome in this case could easily be required by the *Phillips* court's resolution of the wide range of claim-construction issues it is considering; indeed, they recognize that *Phillips* is considering the "very question" presented here. Opp. 5. If *Phillips* were already decided, an opinion that affected the proper analysis of this case—as respondents accept is entirely possible—would require equal treatment of this case, whether through a grant of review here, through a GVR in light of *Phillips*, or through a decision to hold the

petition while this Court reviews *Phillips* itself and then act in accordance with the result of that review. The accident of timing, when a decision in *Phillips* is known to a certainty to be forthcoming, should not produce a different result, terminating petitioner's patent rights when a short delay could preserve those rights.

There are only two possibilities for the effect of *Phillips*. *See* Pet. 29-30. If *Phillips* does not articulate claim-construction principles that require a reconsideration of the ruling in the present case, then review in this case is warranted because the fundamental defects in claim-construction approach on which the ruling here is based will have gone uncorrected. If *Phillips* does articulate claim-construction principles that require reconsideration of the ruling here, then those principles should be applied to this case. This Court should reject respondents' casual dismissal of the interest in correct patent interpretation and fair treatment on which petitioner's patent rights depend.

Petitioner is hardly a mammoth pharmaceutical company with vast numbers of patents, any small number of which might be unimportant. The patents at issue are petitioner's principal assets. Cavalier treatment of the interest in giving proper scope to such patents is inconsistent with patent law's commitment to protecting small commercial entities, not just large commercial ventures.

B. Respondents' second ground for opposing review is entirely extraneous to this petition. Respondents point to the district court's holding of unenforceability in a different case, which is currently on appeal. Opp. 6, citing *Bayer AG v. Housey Pharms., Inc.*, No. 04-1194 (Fed. Cir.) (argued Nov. 3, 2004). Respondents assert that unless the Federal Circuit reverses the district court ruling in *Bayer*, "any dispute about the proper construction of the patents' claims is moot." Opp. 6. This argument is so obviously incorrect that its only residual function in the opposition is one the Court should ignore:

the atmospheric one of tarring petitioner and Dr. Housey, who can hardly explain in this reply brief why the charge of inequitable conduct is so grossly wrong.[2]

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[2] What the district court found to constitute inequitable conduct was the alleged making up of an experiment reported in the patents (Table 3), *Bayer AG v. Housey Pharms., Inc.*, 2003 WL 22953817, ¶¶ 115-117 (D. Del.), *appeal argued Nov. 3, 2004* (Fed. Cir. No. 04-1194). *Contra* Opp. 5. The court centrally relied on its negative view of three other matters, not as inequitable conduct itself, but as reasons not to believe Dr. Housey about his performance of the experiment. Bayer so recognized at oral argument in the Federal Circuit: "secrecy, failing to submit prior art, failing to credit colleagues, those were used as a basis for a credibility determination, not to find inequitable conduct. [The district judge] was very explicit to indicate that she was not finding inequitable conduct on the basis of those points. She simply said these points influence my view of Dr. Housey's credibility . . . ." Housey's appeal in the *Bayer* case directly challenges every aspect of the inequitable-conduct ruling.

Some of the district court's errors are as follows: *First*, the court said there was no documentary corroboration of the experiment, although there plainly was (a date-stamped report of the experimental results). *Id.* ¶ 116. *Second*, the court made clearly erroneous findings about what equipment was available in the laboratory (*id.* ¶¶ 56, 57)—findings urged by Bayer to the district court but in fact lacking any evidentiary support and conclusively disproved by the testimony of Bayer's own witnesses and contemporaneous laboratory notebooks of Bayer witnesses. *Third*, the court carefully listed three reasons for not crediting Dr. Housey's testimony about his experiment, but all three were legally and/or factually incorrect. ¶ 115. **(a)** The court said that Dr. Housey failed to disclose two articles to the PTO, when the articles are disclosed on the face of the patent applications (¶¶ 77, 84) and when, in any event, the court expressly found Dr. Housey did not believe the articles to be material, the essential precondition to disclosure (¶¶ 73, 81). **(b)** The court noted an unidentified failure to acknowledge the contributions of colleagues reflected in a *Cell* journal paper, despite the fact that the paper was submitted to the PTO and on its face discloses the colleagues' contributions (¶¶ 34, 46) and when the only relevant *patent-law* issue with colleagues' contributions was possible co-inventorship, yet the putative co-inventors *conceded* that they were not co-inventors of the invention as Dr. Housey genuinely understood it (¶¶ 85, 86). **(c)** Most importantly (because the court said this was the backdrop for its other assessments, ¶ 107), the court

This case is not moot. Respondents' naked assertion of present mootness not only is unaccompanied by any citation of precedent. It is indisputably wrong. The parties to this case have a present, live stake in the outcome of the claim-construction ruling, with its invalidity and non-infringement consequence, at least as long as the inequitable-conduct issue remains in pending litigation, as respondents recognize it is. That simple fact fully answers respondents' mootness contention. Indeed, if the case were moot now, the required result would be a vacatur of the decisions below with instructions to dismiss (subject of course to reinstatement if the inequitable-conduct ruling in *Bayer* were set aside). *United States v. Munsingwear*, 340 U.S. 36 (1950). Respondents do not suggest such a disposition.

Not only is the case obviously not moot, but there are several necessary (if not sufficient) contingencies that would have to occur (over an extended period) before the claim-construction issue presented for review could become moot. *First*, the Federal Circuit would have to affirm the district court's ruling of unenforceability for inequitable conduct in

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fundamentally misunderstood patent law in *condemning* Dr. Housey's efforts to keep his patent-specific work secret from others in the university laboratory, when those efforts undisputedly were undertaken on advice of counsel and (as Bayer did not dispute on appeal) such pre-application secrecy is positively demanded by patent law in order to *preserve* the right to priority both abroad and in the United States (*e.g.*, 35 U.S.C. § 102 (public use or knowledge defeats novelty)). *Finally*, based upon its three legally and/or factually incorrect reasons for not crediting Dr. Housey's testimony about his experiment (which included no inconsistencies or evasiveness in the testimony), the court found that it had no alternative but to conclude that Bayer had proved by clear and convincing evidence that the Table 3 experiment was not performed, even though Bayer, with the burden of proof, did not undertake the essential step of proving the numbers *inaccurate* by attempting the very simple task of replicating the experiment. (As noted below, *see* note 4, *infra*, petitioner, after the shock of the district court's adverse finding, quickly undertook a replication and confirmed the *accuracy* of the Table 3 numbers.)

the *Bayer* case, and that ruling would have to become finally unreviewable (after any rehearing and certiorari proceedings). Petitioner has presented strong arguments in the *Bayer* appeal for setting aside the district court's inequitable-conduct ruling as infected by legal error and clearly erroneous. *See* note 2, *supra*. Respondents are aware, if only from their own citation of *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358 (Fed. Cir. 2003) (cited Opp. 6), that the Federal Circuit carefully examines and frequently reverses findings of inequitable conduct.[3] Accused infringers so commonly make such charges in order to "deprive patentees of their earned property rights and impugn fellow professionals" that they "have been called a 'plague' on the patent system." *Molins*, 48 F.3d at 1182.

Second, even if the inequitable-conduct ruling in the *Bayer* case were ultimately to survive, that would not settle the matter for the respondents in the present case. These respondents have no inequitable-conduct ruling in their favor: they dropped their inequitable-conduct defenses, without prejudice, to secure the final judgment of invalidity and non-infringement. Pet. App. 25a-26a. Accordingly, they would have to return to the district court in this case—should the claim-construction ruling be set aside, which automatically

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[3] In addition to *Dayco*, cases involving complete or partial reversals of inequitable conduct determinations include *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333 (Fed. Cir. 2003); *Florida State Bd. Of Educ. v. American Bioscience, Inc.*, 333 F.3d 1330 (Fed. Cir. 2003); *Hoffmann-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354 (Fed. Cir. 2003); *Juicy Whip, Inc. v. Orange Bang, Inc.*, 292 F.3d 728 (Fed. Cir.), *cert. denied*, 537 U.S. 1019 (2002); *Akron Polymer Container Corp. v. Exxel Container, Inc.*, 148 F.3d 1380 (Fed. Cir. 1998); *Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573 (Fed. Cir. 1997); *Allied Colloids Inc. v. American Cyanamid Co.*, 64 F.3d 1570 (Fed. Cir. 1995); *Molins PLC v. Textron, Inc.*, 48 F.3d 1172 (Fed. Cir. 1995); *Halliburton Co. v. Schlumberger Technology Corp.*, 925 F.2d 1435 (Fed. Cir. 1991); *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867 (Fed. Cir. 1988).

would dissolve the stipulation of invalidity and non-infringement—and then re-raise their inequitable-conduct defense. They have no such claim in this case now, and so an inequitable-conduct ground *could* not moot the present issue until *after* review of the claim-construction ruling presented here.[4] In short, there plainly is no mootness today, and any possible mootness would occur well down the road, and only after review of the claim-construction ruling challenged in the present petition.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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[4] Presumably respondents would invoke issue preclusion to gain the benefit of any final *Bayer* ruling, but whether issue preclusion would apply, a matter for initial district court decision, is hardly a foregone conclusion, if only because preclusion here would be "inequitable" (Restatement Second of Judgments § 28(2); *National R.R. Passenger Corp. v. Pennsylvania*, 288 F.3d 519, 528 (3d Cir. 2002), *cert. denied*, 538 U.S. 1057 (2003)). The most powerful evidence that Dr. Housey in fact performed the experiment at issue (*see* note 2, *supra*) is that, after the district court rendered its shocking finding of fabrication, he had an aide conduct a replication of the experiment (insofar as he had the materials) and confirmed the accuracy of the detailed numbers reported in the patents—numbers that simply *could not* have been made up (as Bayer alleged) if they could be accurately reproduced, as they now have been.